Standard Operation Procedures	SOP_001_S
Effective Date: 21/06/2022	**Public**

Pre-submission activities

Special Requirements	This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls. Please note that this document becomes uncontrolled once printed. Make sure by always referring only to the that you have the right version in use. Deviations from the provision of this document need to be recorded in the Exception Request Workflow. The procedure should be updated when there are changes in EFSA with respect to what is stated in the document (e.g. Relevant Standards, legislation, and documents, change in procedure, etc.). The person responsible for maintaining this procedure up to date is the Lead author with the support of the QM.

Process Responsibility	Process owners are accountable this procedure being adhered to within their respective or unit. All relevant staff is responsible for the correct implementation of the procedure. Responsibilities for performing specific steps are outlined in the document.

SCOPE AND OBJECTIVES

This Standard Operating Procedure (SOP) describes the three processes preceding the possible submission of an application by the applicant to the EC/MS, and the related mandate to EFSA, for the risk assessment or peer-review of an application.

The processes in scope are: General Pre-submission Advice (GPSA), Renewal Pre-submission Advice (RPSA) and Notification of Studies (NoS). Each process is directly mandated by Article 32(a), (b), (c) of Regulation (EC) No 178/2002 and aims to enhance the degree of Quality and Transparency of risk assessment/peer-review.

In detail, this procedure applies to all instances where, as per Article 32 (a), (b), (c) of Regulation (EC) No 178/2002 and in line with the Practical Arrangements on pre- submission phase and public consultations, a potential applicant submits a request to EFSA for pre-submission advice and/or notifies studies commissioned to a laboratory or testing facility/carried out in internal testing facility or intended for commissioning/carrying out (applicable to renewals only).

This SOP describes steps related to the process 1.1 GPSA and 1.2 RPSA

RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

- EFSA's Founding Regulations 178/2002
- Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC
- COMMISSION NOTICE on the submission of notifications under Articles 13 and 17 of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and under the relevant provisions of Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 (2021/C 80/01)
- IMPRUL_111_PAs-pre-submission-phase-and-public-consultations.
- IMPRUL_109_PAs-transparency-and-confidentiality
- NoS User guide
- SOP_012_S RA of Applications
- SOP_013_S RA Pesticides
- SOP_019_S Public Consultation
- SOP_020_M Confidentiality decision making

ABBREVIATIONS AND DEFINITION

Application	Applications, so-called "Regulated product", means the claim, process, product, substance or organism which is the subject matter of an intended or submitted given application for which Union law contains provisions for EFSA to provide a scientific output, including a scientific opinion.
Customer Portal	EFSA's customer portal is built on Salesforce Customer Relationship Management Software. It is the single portal to all external stakeholders, including EC/EP/MS
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GMO	Evaluation of Genetically Modified Organisms
GPSA	General Pre-Submission Advice
Laboratory/ Testing facility	Natural or legal persons carrying out the study, i.e. the experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data with respect to the properties and/or the safety of that test item, which is relevant for submission to appropriate regulatory authorities.
MS	Member State
NoS	Notification of Studies
	The portal becomes, the single public interface for all information

Open EFSA Portal	related to EFSA's scientific work. Closely following the risk assessment process from receipt of the dossier to adoption of the opinion, it integrates information coming from different platforms, such as Case Management Tool, e- submission tool, Customer Portal or Talent Management, making available the documents produced and used in the process, including non-confidential data. It includes information on the status of assessments, dossier and studies (non-confidential versions), meetings' agenda and minutes, info on experts, etc.
MRL	Maximum Residues Level
PAs	EFSA's Practical Arrangements implementing the provisions of the Transparency Regulation
PPP	Plan Production Product
RA	Risk Assessment
RMS	Rapporteur Member State
Co-RMS	Co-Rapporteur Member State
SMU	Subject Matter Units
SOP	Standard Operating Procedure
WIN	Working Instructions
FDP	Front Desk & Work force Planning • Provides front-desk services to risk managers (European Commission, European Parliament and Member States) and business operators on application dossiers, up to the validation of the application and/or mandate. • Delivers pre-submission advice on the notification of studies and application dossiers • Oversees the interaction and provision of services to risk managers/requestors concerning generic mandates • Coordinates the receipt and oversees the acceptance of incoming mandates, dossiers and other tasks • Plans and oversees the deployment of the scientific workforce
Potential Applicant	Any private or legal person that can profit from or is subject to pre-submission activities
PROCEDURE	
	Previous SOPs in the process:
PROCESS 1	GENERAL PRE-SUBMISSION ADVICE (GPSA)
Step 1	1.0 Receipt and acceptance of GPSA request
	1.1 The potential applicant who does not already have an account registers directly in the Customer Portal and FDP validates the registration. 1.2 Unless already obtained previously (e.g. in the context of another pre-submission activity), the registered potential applicant must request the provisioning of a pre-application identification (ID)

Potential Applicant, FDP	that would be automatically assigned in relation to the specific regulated product in a given regulated product area (for which GPSA could be requested). 1.3 At any time prior to the submission of the envisaged application, the potential applicant may request GPSA through the dedicated online form – provided that the request does not exceed the limit of two GPSAs per pre- application ID[1]. 1.4 Within 15 working days from the receipt of the GPSA form, FDP verifies whether the request is in accordance with the provisions of Art. 32a(1) of Regulation (EC) No 178/2002 and Articles 6 and 7 of the IMPRUL_111_PAs-pre- submission-phase-and-public-consultations. GPSA shall relate exclusively to the relevant requirements set out in the applicable rules and guidance documents or guidelines. Aspects going beyond the information available in the rules and guidance documents or guidelines applicable to applications shall be out of scope. Questions on the design of the study, unless the advice concerns guidance documents developed by EFSA in which study design is addressed are also out of scope. Questions on proposed design and hypothesis to be tested are always out of scope (even if mentioned in guidance documents developed by EFSA). 1.5 No later than 15 working days from receipt, FDP informs the potential applicant whether the request is accepted or rejected. 1.6 In case of rejection, FDP explains the reasons for rejecting and invites the potential applicant to resubmit the form[2]. Rejected requests shall not be considered for the calculation of the maximum number of general pre- submission advice. **Special and exceptional provisions applicable to the area of PPP, MRL and GMO Directive 2001/18** The following changes are applied to the workflow: • Upon receipt of the GPSA form, FDP shall transmit the request to the relevant National Competent Authorities indicated by the potential applicant, e.g. (intended) RMS[3]/(intended) co-RMS/(intended) EMS. • For intended applications for approval of new substances and/or for intended applications for maximum residue levels of pesticides within the EU, should the requester(s) fail to indicate the intended National Competent Authorities, EFSA shall provide the GPSA alone, the potential applicant is informed accordingly. • For intended applications for renewals of existing substances and intended applications for import tolerance, should the requester(s) fail to indicate the intended National Competent Authorities, EFSA must reject the GPSA request. The requester can submit a new request. • For intended notification in line with Articles 13 and 17 of the GMO Directive 2001/18, the requester is recommended to include in the GPSA request to EFSA an indication of the MS to which it intends to submit the product notification, so that this MS may participate

[1] Using the pre-application ID, the Customer Portal automatically checks whether the potential applicant has already received two GPSA from EFSA on the same pre-application ID. In that case, the system directly prevents the potential applicant from submitting any further GPSA request.
[2] In case of rejection due to more than two GPSA requests per pre-application ID, the resubmission of the form will not apply.
[3] Providing information of the designated RMS is mandatory for applications for renewal.

	in the provision of the GPSA. This should not prevent the requester from submitting its product notification to a MS different from the one indicated in the request of GPSA[4]. • No later than 15 working days from the receipt, FDP informs the National Competent Authorities whether the request is accepted or rejected and whether it will be addressed in writing or during a meeting.
Step 2	2.0 Provision of GPSA
FDP, RMS/EMS, Potential Applicant	2.1 Once the GPSA request is accepted, FDP decides upon the most appropriate manner to address the questions and to deliver its advice. 2.2 By default, the advice will be given in written form by FDP within 15 working days from the acceptance. 2.3 However, in case a discussion with the potential applicant is considered useful to clarify specific aspects of the request, FDP will organise a meeting within 20 working days from the acceptance of the request, preferably via tele/videoconference. The advice is provided during the meeting. 2.4 In both circumstances above (2.2 and 2.3), FDP must also draft a succinct summary of the given advice and send it to the potential applicant for information. The summary is sent together with the written advice or after the meeting and disclosed, pursuant to article 38(1)(i) of the GFL, only upon validation of the related dossier (if any). Please refer to SOP_012_S RA of Applications and SOP_013_S RA Pesticides. The names of the officers involved in the GPSA must be recorded to ensure the segregation of tasks between who provided GPSA and the staff performing the validity check and the risk assessment (please refer to SOP_012_S RA of Applications and SOP_013_S Pesticides). **<u>Special and exceptional provisions applicable to the area of PPP, MRL and GMO Directive 2001/18</u>** The following changes are applied to the workflow: • In case of written advice: ○ EFSA shall prepare the written advice and the related summary in close cooperation with the National Competent Authorities. ○ The written advice and the related summary shall be provided to the requester(s) within 20 working days as of the date of the acceptance of the request. ○ If the National Competent Authorities disagree with EFSA about one or more replies, the written advice and the summary shall reflect both opinions. • In case a discussion with the potential applicant is considered useful to clarify specific aspects of the request: ○ EFSA shall prepare the meeting in close cooperation with the National Competent Authorities. The meeting shall be organised within 20 working days as of the date of the acceptance of the request; both

[4] Section 2 of the Commission adopted Notice 2021/C 80/01

	EFSA and the National Competent Authorities shall attend. The advice is given during the meeting. ○ After the meeting, EFSA shall prepare a summary in close cooperation with the National Competent Authorities and send it to the requester for information. ○ In case the National Competent Authorities disagree with EFSA about one or more replies provided to the potential applicant during the meeting, the summary shall reflect both opinions. EFSA shall then share the written advice and the summary with the Competent Authorities of all Member States for information. The summary is disclosed, pursuant to article 38(1)(i) of the GFL, only upon validation of the related dossier (if any). Please refer to SOP_013_S Pesticides.
PROCESS 2	RENEWAL PRE-SUBMISSION ADVICE (RPSA)
Step 1	1.0 Submission of the intended list of studies
Potential Applicant	1.1 Please refer to step 1.1 of process 1 above. 1.2 Unless already obtained previously (e.g. in the context of another pre-submission activity), the registered potential applicant must request the provisioning of a pre-application identification for renewal that EFSA would assign in relation to the specific regulated product in a given regulated product area (for which the RPSA will be obtained). 1.3 Before submitting an application for the renewal of authorisation or approval, potential applicants shall mandatorily – as per Article 32c(1) – submit to EFSA the list of new studies they intend to carry out to support the renewal application, including information on their design (see NoS procedure below and PAs on the pre-submission phase and public consultations for more details).
Step 2	2.0 Launch of public consultation on the intended studies
FDP	2.1 Upon receiving the list of intended studies, FDP performs within 10 working days the administrative check of information – information requirements outlined in Article 12 of the PAs on pre-submission phase and public consultation – and, if needed, requests supplementary information to the potential applicant. 2.2 The potential applicant, within a certain deadline set by FDP, shall then provide the requested supplementary information. If FDP receives the missing information, the 10 working days for the administrative check shall re-start as of the date of this second submission. 2.3 FDP shall launch, within 10 working days from the conclusion of the administrative check, the consultation of third parties on the intended studies for renewal, as per Article 32c(1) (see SOP_019_S Public Consultation for more details).

Step 3	3.0 Provision of RPSA

FDP, SMU	3.1 Without delay after the closure of the consultation, the comments are automatically published on the Open EFSA.
	3.2 FDP screens the comments received and sends them to the SMU.
	3.3 Following the comments' review, the SMU decides upon the most appropriate manner to address the questions and to deliver its advice.
	3.4 By default, the advice will be given in written form by the SMU within 30 working days from the closure of the public consultation.
	3.5 In case a discussion with the potential applicant is considered useful to clarify specific aspects of the request, the SMU may organise a meeting within 30 working days from the closure of the consultation, preferably via tele/videoconference.
	3.6 In both circumstances above (3.4 and 3.5), the SMU shall draft a summary of the given advice, which includes the results of the public consultation, i.e. how comments are taken into account, and send it to the potential applicant for information. The summary is sent together with the written advice, or maximum 8 working days after the meeting, if the advice was given during a meeting. The summary is disclosed, pursuant to article 38(1)(i) of the GFL, only upon validation of the related dossier (if any). Please refer to SOP_012_S RA of Applications and SOP_013_S Pesticides.
	3.7 The officers involved in the RPSA must be recorded to ensure the segregation of tasks between who provided RPSA and the staff performing the validity check and the risk assessment (please refer to SOP_012_S RA of Applications and SOP_013_S Pesticides).
	3.8 **Special and exceptional provisions applicable to the PPP, MRL and GMO Directive 2001/18**
	
	The following changes are applied to the workflow:
	• FDP shall provide the National Competent Authorities with the information notified by the potential applicant and the comments received during the consultation of third parties.
	• SMU informs the National Competent Authorities whether RPSA will be provided in writing or during a meeting.
	• In case of written advice:
	  • EFSA shall prepare the written advice and the related summary in close cooperation with the National Competent Authorities;
	  • The written advice and the related summary shall be provided to the requester(s) within 30 working days after the closure of the consultation of third parties
	  • If the National Competent Authorities disagree with EFSA about one or more replies, the written advice and the summary shall reflect both opinions;
	• In case a discussion with the potential applicant is considered useful to clarify specific aspects of the request:
	  • EFSA shall prepare the meeting in close cooperation with the National Competent Authorities. The meeting shall be organised within 30 working days after the closure of the

	consultation of third parties; both EFSA and the National Competent Authorities shall attend. • After the meeting, EFSA shall prepare a summary in close cooperation the National Competent Authorities. • In case the National Competent Authorities disagree with EFSA about one or more replies provided to the potential applicant during the meeting, the summary shall reflect both opinions. EFSA shall then share the written advice and the summary with the Competent Authorities of all Member States for information. The summary is disclosed, pursuant to article 38(1)(i) of the GFL, only upon validation of the related dossier (if any). Please refer to SOP_013_S Pesticides.
PROCESS 3	NOTIFICATION OF STUDIES (NOS)
Step 1	1.0 Submission of Notification
Potential Applicant/ laboratory or testing facilities	1.1 Please refer to step 1.1 of process 1 above. 1.2 At any time [5] prior to the submission of an application, the registered potential applicant/ laboratory or testing facilities enter the NoS database and initiates a notification by providing information on the commissioned studies, including their title and scope (for more details see NoS user guide). 1.3 After having specified all mandatory information (as per Article 32b and Article 20 of the Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultation applications), potential applicant/ laboratory or testing facilities are entitled to proceed with the submission of the final notification into the NoS database. 1.4 Reported potential applicant/ laboratory or testing facilities may co-notify – i.e. submit the same notification in which they are cross-referenced, fulfilling the legal requirements or Article 32b. 1.5 In case of renewal applications, see process 2
	Following SOPs in the process: • SOP_012_S RA of Applications • SOP_013_S Pesticides • SOP_019_S Public Consultations • SOP_020_M Confidentiality decision making

[5] Potential Applicants might initiate a notification before or after requesting a GPSA, or not request it at all as GPSA is not mandatory. Necessarily, however, studies must be notified without delay before the study starting date.